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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,222	12/05/2003	Peter G. Klimko	2443 US	9553

7590 12/29/2008

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EXAMINER	
FAY, ZOHREH A	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
12/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/729,222	KLIMKO ET AL.	
	Examiner	Art Unit	
	ZOHREH A. FAY	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 7, 2008 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103 as being unpatentable over Mayfroy-Camine et al., LaHaye et al., Campbell et al. (6,177,419), Crapo et al. and Winkler et al. (Molecular Vision 1999).

Mayfroy-Camine et al. teach the use of the claim-designated compounds as antioxidants, for treatment of diseases by acting as free radical scavenger. See the abstract and column 6, lines 36-67. Lahoy et al. teach the use of free radical scavengers and antioxidants for the treatment of macular degeneration. See column 4, lines 34-40. Winkler et al. teaches the role of oxidation in relation to macular degeneration and the effect of superoxide dismutase in preventing oxidative damage. See the abstract. Campbell et al. teach the use of the claimed compounds in a pharmaceutical formulation as mimetic of superoxide dismutase, which can be used by any appropriate route of administration such as injection. See column 2, lines 22-46. The above reference differs from the claimed invention in the use of the compounds for the treatment of disorders such as macular degeneration. Crapo et al. teach the compounds of similar structure with porphyrin ring, which are SOD mimetic, can be used for the treatment of disorders such as glaucoma and macular degeneration. It would have been obvious for a person skilled in the art to use a compound having SOD mimetic activity for the treatment of macular degeneration, considering that Crapo et al.

teach the use of similar compounds with SOD mimetic activity for the treatment of macular degeneration.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the claimed compounds having Super oxide dismutase activities and the others relate to the use of compounds with superoxide dismutase activities for the treatment of macular degeneration.

Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Applicant in his remarks argues that Malfroy-Camine does not teach the use of compound A to treat retinal maladies. The arguments are not well taken. Malfroy-Camine is cited to show the antioxidant and superoxide dismutase activity of the claimed compounds. Applicant also argues that Wrinkle does not provide a detailed discussion of the treatment of AMD, much less the use of SOD mimetics to treat AMD. The arguments are not well taken. Obviousness does not require a detailed discussion. The mere suggestion that there is a correlation between oxidation and macular degeneration and the effect of superoxide dismutase in preventing oxidative damage make the Winkler a valid reference for obviousness rejection. See In Re Lambert and Knort, 192 USPQ 278 (CCPA 1976) at 280 where the court stated " the question under 35 U.S.C. 103 is not what the references explicitly teach, but what they would have suggested to one skilled in the art at the time the invention was made." Applicant also alleges criticality to the smaller molecules of the present invention in comparison with the larger molecules of Campbell and Crapo. The allegation is not well taken. Campbell is cited to show that injection is a routine route of ophthalmic

administration. Crapo is cited to show that compounds having superoxide dismutase activity have been previously used for the treatment of AMD. Applicant's arguments regarding the different mechanism by which, Crapo achieve superoxide activity have been noted, but are not deemed to be persuasive. The mechanism by which the compounds demonstrate their superoxide activity does not create a patentably distinct invention in the absence of evidence to the contrary. In conclusion: the primary reference was used to show the anti-oxidant and superoxide dismutase active of the claimed compounds. The secondary reference was used to show that there is a correlation between oxidation and macular degeneration, and the effect of superoxide dismutase in preventing oxidative damage. The secondary references also were used to demonstrate that the small or large compounds having superoxide dismutase activity have been previously used for the treatment of AMD. The above references teach that the claimed compounds have superoxide dismutase activity. The relied upon references also teach the general concept of the correlation between macular degeneration and oxidation and the use of compounds with super dismutase activity in preventing oxidative damage. Thus, it would have been obvious to a person skilled in the art to use the claimed compounds having superoxide dismutase activity for the treatment of conditions associated with oxidative damage such as AMD in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF
/Zohreh A Fay/
Primary Examiner, Art Unit 1612